Zacks Small-Cap Research

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Jason Napodano, CFA
John Tucker, PhD
312-265-9421 / jnapodano@zacks.com

scr.zacks.com
111 North Canal Street, Chicago, IL 60606

Neurocrine Biosciences, Inc.

(NBIX-NASDAQ)

NBIX: NBI-98854 Offers Mixed Data From Phase 2b In TD…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	06/16/2010
Current Price (10/30/13)	$10.36
Target Price	**$14.00**

UPDATE

On October 29, 2013 Neurocrine reported financial results for the third quarter. R&D spending was somewhat less than expected, and the company now guides to a loss of $0.70 per share in 2013, down from previous guidance to a loss of $0.75 to $0.83 per share.

Upcoming catalysts in December include the results of the open phase interval of the KINECT-1 trial, top-line results from the KINECT-2 trial, and data from drug-drug interaction and hepatic impairment studies. We do not expect these to strongly influence the share price as the main KINECT-1 and KINECT-2 studies are being performed at what now appears to be too low a dose. Nonetheless, trends in the data may be suggestive of the likelihood of developmental success for NBI-98854.

SUMMARY DATA

52-Week High	**$16.70**
52-Week Low	**$6.88**
One-Year Return (%)	**41.14**
Beta	**0.45**
Average Daily Volume (sh)	**882,278**
Shares Outstanding (mil)	**67**
Market Capitalization ($mil)	**$716**
Short Interest Ratio (days)	**2.54**
Institutional Ownership (%)	**87**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**36.2**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**13.9**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**N/A**

Risk Level	**Below Avg.**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	11.3 A	10.6 A	9.4 A	21.9 A	53.1 A
2013	0.7 A	0.7 A	0.7 A	0.8 E	2.9 E
2014					5.0 E
2015					50.0 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.01 A	-$0.01 A	-$0.05 A	$0.14 A	$0.08 A
2013	-$0.18 A	-$0.18 A	-$0.17 A	-$0.17 E	-$0.69 E
2014					-$0.52 E
2015					-$0.02 E

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WHAT'S NEW

Recent Financial Results

On October 29, 2013, Neurocrine Bio reported financial results for the third quarter 2013. The company reported total revenues in the quarter of $0.73 million, essentially in-line with our expectation at $0.75 million. Research and development expenses of $9.5 million and G&A expenses of $3.2 million each came in slightly below expectations, at $9.5 million and $3.2 million, respectively. The reduction in R&D expenses was attributed to the shifting of certain NCI-98854 activities from FY 2013 to FY 2014 in light of the need to examine higher doses. The company reported a loss of $11.1 million ($0.17 per share) for the quarter, close to our projection of $12.3 million ($0.18 per share). The increased loss compared to the same quarter in 2012 ($4.0 million) resulted mainly from the reduction of collaboration revenue from AbbVie and Boehringer Ingelheim. The participatory phases of each of these collaborations ended as planned during 2012.

…Financial Guidance…

The company's balance sheet on March 31, 2012 reflected total assets of $166.0 million, including cash and short-term investments of $156.9 million and current assets of $159.2 million. We note the company has another $5.0 million in long-term investments and restricted cash. Financial guidance for 2013 was updated, in part to reflect these lower-than-expected expenditures. Management now expects to end 2013 with approximately $145 million in cash, investments, and receivables, compared to prior guidance of $130 million. The net loss for 2013 is now expected to be $46 million to $47 million ($0.70 per share) compared to prior guidance of $50 million to $55 million ($0.75 to $0.83 per share).

Clinical Updates

…Elagolix…

Abbott initiated the second of two Phase 3 trials in endometriosis in August 2013. On their quarterly earnings conference call this week, they announced that they expect to have top-line results from the first trial, dubbed Violet-Petal, in the latter half of 2014. Violet-Petal is a 24-week, multinational, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of elagolix in 875 women, age 18 to 49, with moderate to severe endometriosis-associated pain. Approximately 160 sites in the United States, Puerto Rico and Canada are conducting this study. The second Phase 3 trial is of similar in design to the Violet Petal Study and will assess 788 women, age 18 to 49, with moderate to severe endometriosis-associated pain at more than 200 sites globally. We note that AbbVie is also currently conducting a Phase 2b study of elagolix in uterine fibroids. This study is assessing uterine blood loss in 280 women with heavy uterine bleeding due to uterine fibroids. We believe that AbbVie could have these phase 2b data shortly, although whether or not they will disclose or present the data to investors remains to be seen.

…VMAT-2 Program…

Neurocrine's VMAT-2 program is evaluating the safety and utility of the VMAT inhibitor NBI-98854 in the treatment of patients with tardive dyskinesia arising from neuroleptic drug use. Top-line results were reported in September 2013 for the KINECT-1 trial, which evaluated NBI-98854 in subjects with schizophrenia or schizoaffective disorder. The KINECT-2 trial is evaluating NBI-98854 in patents whose neuroleptic drug use is due to any of a broader array of disorders, including schizophrenia, schizoaffective disorder, a mood disorder, or a gastrointestinal disorder.

On the October 29 earnings call, management disclosed several interim results from the KINECT-2 trial, which remains blinded as to assignment to the treatment group assignments:

- Randomization of the trial is complete (The trial was closed to enrollment on October 25th according to clinicaltrials.gov). Thus top-line results should be available by mid-December 2013.
- The discontinuation rate to date is under 20%. While this is difficult to objectively assess without a detailed knowledge of average duration of therapy to date, it was described by management as "low".

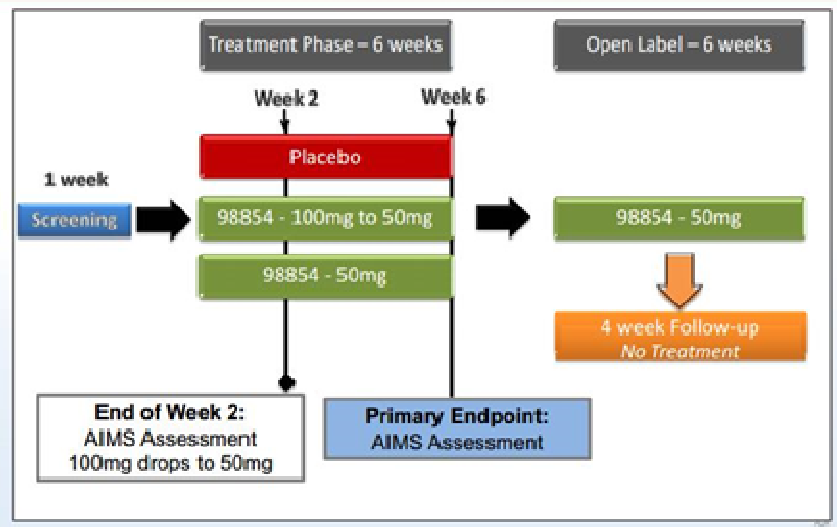
- Adverse effect rates for patients whose exposure to neuroleptics is due to a diagnosis of a mood disorder or gastrointestinal disorder are similar to those observed in KINECT-1 for patients with schizophrenia or schizoaffective disorder.
- At each of the scheduled dose titration decision time points (Week 2 and Week 4), about 80% of subjects are having their dose increased. We remind readers that for each time point, the criteria for increasing dose (from 20 mg to 50 mg at Week 2 and from 50 to 75 mg at Week 4) is that the subject is still experiencing dyskinesia and is tolerating their current dose. We regard the increase in dose as a good sign.

A Brief Reminder of the KINECT-1 Results

The design of the KINECT-1 study is described in the Figure below. Subjects with moderate-to-severe neuroleptic-induced tardive dyskinesia and a diagnosis of schizophrenia or schizoaffective disorder were randomized to one of two treatment arms:

- Arm 1: 50 mg of NBI-98854 daily for 6 weeks
- Arm 2: 100 mg of NBI-98854 daily for 2 weeks followed by 50 mg daily for 4 weeks

The primary endpoint of the trial was the change from baseline in the Abnormal Involuntary Movement Score (AIMS) at Week 6 as determined by on-site raters. A key secondary endpoint was clinician-assessed improvement in tardive dyskinesia, as assessed on a 7-point scale. The study randomized 109 subjects (Placebo: 54; 50 mg: 27; 100 mg: 26) at 33 sites around the U.S.



A total of four patients from the intend-to-treat (ITT) population (one on 50 mg and three on 100 mg) were later determined to have never received drug. Thus in addition to the ITT analysis, Neurocrine also analyzed the data on a per protocol (PP) basis, excluding data from these four patients. Neither arm of the trial achieved its primary endpoint of providing a statistically significant improvement in the AIMS score at Week 6. However, examination of the Week 2 data showed that subjects in Arm 2, receiving 100 mg of NBI-98854, exhibited a nominally statistically significant improvement from baseline in the AIMS when evaluated by a central reviewer. Scores assigned by on-site reviewers were not significantly improved.

		Week 6		
		PBO	50mg	p-value
AIMS Change from Baseline (on-site assessment)				
	LS Mean AIMS ANCOVA (ITT)	-2.5	-3.3	ns
	LS Mean AIMS ANCOVA (PP)	-2.4	-3.0	ns
	Responder Rate (ITT)*	11%	24%	ns
	Responder Rate (PP)*	10%	21%	ns
AIMS Change from Baseline (video assessment)				
	LS Mean AIMS ANCOVA (ITT)	-2.2	-3.5	ns
	LS Mean AIMS ANCOVA (PP)	-1.9	-3.3	ns
	Responder Rate (ITT)*	21%	29%	ns
	Responder Rate (PP)*	18%	28%	ns

** a responder is defined as 50% reduction in AIMS*

		Week 2				
		PBO	50mg	p-value	100mg	p-value
AIMS Change from Baseline (on-site assessment)						
	LS Mean AIMS ANCOVA (ITT)	-1.2	-2.1	ns	-2.1	ns
	LS Mean AIMS ANCOVA (PP)	-1.3	-2.4	ns	-2.5	ns
	Responder Rate (ITT)*	7%	7%	ns	12%	ns
	Responder Rate (PP)*	7%	8%	ns	14%	ns
AIMS Change from Baseline (video assessment)						
	LS Mean AIMS ANCOVA (ITT)	-2.7	-3.9	ns	-4.8	0.034
	LS Mean AIMS ANCOVA (PP)	-2.7	-3.9	ns	-5.5	0.008
	Responder Rate (ITT)*	23%	30%	ns	40%	ns
	Responder Rate (PP)*	23%	31%	ns	48%	0.034

** a responder is defined as 50% reduction in AIMS*

Based on previous clinical work, Neurocrine believed that the 100 mg dose would be the maximum tolerated dose. However, the results of the KINECT-1 trial seem to indicate that schizophrenic and schizoaffective patients with moderate-to-severe TD tolerate NBI-98854 better than healthy volunteers. For example, the frequency of treatment-emergent adverse events during the initial two-week period was 17%, 18% and 15% in the placebo, 50mg and 100mg groups, respectively. During the six-week treatment period the frequency of treatment-emergent adverse events was 37% for placebo and 26% for NBI-98854. There were no drug related serious adverse events. Below is a snap-shot of the adverse event profile:

AE	Placebo	50 mg	100 mg
Somnolence	0	2	1
Dry mouth	2	0	0
Bronchitis/URI	2	0	0

In secondary assessments of efficacy, including analysis based on a responder rate and Clinical Global Impression – Tardive Dyskinesia (CGI-TD). Treating clinicians determined that 36% of the subjects taking 100 mg of NBI-98854 were "much improved" or "very much improved" at Week 2 compared to only 8% of the placebo subjects (p=0.002) in this pre-specified key secondary efficacy endpoint. This analysis was performed by a group of assessors that was distinct from those performing the AIMS assessment, and was performed without access to the AIMS results. Below is a snap-shot of the CGI-TD data:

		Week 2				
CGI-TD		PBO	50mg	p-value	100mg	p-value
	LS Mean Score	3.6	3.2	ns	3.0	0.007
	Responder Rate*	8%	15%	ns	36%	0.002

*a responder is defined as "much improved" or "very much improved"

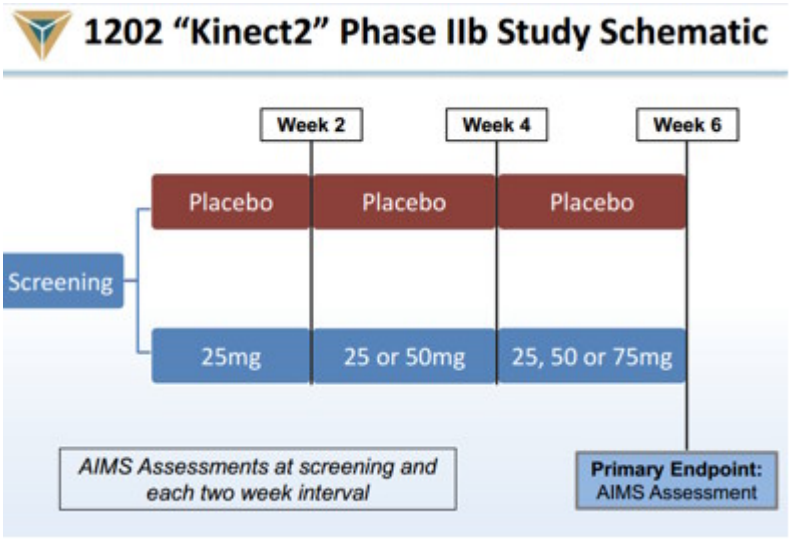
		Week 6		
CGI-TD		PBO	50mg	p-value
	LS Mean Score	3.2	3.3	ns
	Responder Rate*	22%	23%	ns

*a responder is defined as "much improved" or "very much improved"

Overall, the data from the KINECT-1 study is compatible with the hypothesis that higher doses would provide better efficacy and still be well-tolerated. However, this conclusion is based on post-hoc analysis and is supported by the central reviewer AIMS data only. Thus, while we do not expect the KINECT-2 trial to hit its primary endpoints, the data is of interest for its potential to confirm or contradict the preliminary conclusion that the failure of KINECT-1 was due to the use of insufficiently high doses.

KINECT-2

The KINECT-2 trial is evaluating NBI-98854 in patents whose neuroleptic drug use is due to any of a broader array of disorders, including schizophrenia, schizoaffective disorder, a mood disorder, or a gastrointestinal disorder. Subjects are randomized to receive placebo or NBI-98854 in a dose-titration protocol. At Weeks 2 and 4 those who are tolerating their current dose and whose response to treatment is incomplete are up-titrated to a higher dose (75 mg maximum). The primary endpoint of the trial is AIMS assessment at Week 6.



Although management has remains blinded to treatment assignment, the disclosures provided in the Q3 earnings call provide some incremental support for the hypothesis that KINECT-1 failed due to inadequate dosing:

- Management reports that overall adverse event rates for subjects with non-schizophrenia related diagnoses in KINECT-2 is similar to those seen for those with schizophrenia-related diagnoses in KINECT-1. That's good news, because a large difference would be difficult to explain.
- Thus far, the percentage of patients undergoing up-titration from the 20 mg to the 50 mg dose at Week 2 is about 80%. Similarly, about 80% are up-titrating from 50 to 75 mg at Week 4.The similarity of the rate at which patients fail to up-titrate from 20 to 50 mg or from 50 to 75 mg is reminiscent of the ca. 20% adverse event rate seen in the placebo and both active treatment arms of KINECT-1. One plausible interpretation of these results is that all of these patients are under-dosed.

Looking Forward to December Catalysts and KINECT-3

Management has disclosed that the planned KINECT-3 (not the official name, just what we are calling it) study will look very similar to KINECT-1, only with doses starting at 100 mg and perhaps even moving to 200 mg. CEO Kevin Gorman noted on the call that the company has a lot of flexibility here based on the tolerability and safety data found in KINECT-1, and thus far, apparently in KINECT-2 as well.

Several additional data points will read out in mid-December that will help inform the KINECT-3 trial as well as provide additional insights into NBI-98854's potential for developmental success. The KINECT-1 trial continues with a 6 week open label treatment regimen using a dose of 50 mg per day in all previously randomized subjects. Additional assessments will be performed 2 and 4 weeks after the end of this open label treatment regimen. As noted above, top-line results from the KINECT-2 trial are expected about the same time. Lastly, management has guided to the release of safety data from hepatic impairment and drug-drug interaction studies at around the same time. Given that the doses used in the efficacy trials are probably too low, we don't expect a huge amount of information content from these trials, though trends in the data may be suggestive of what might be expected from KINECT-3.

Lastly, the company has initiated preclinical studies to support the advancement of NBI-98854 into clinical trials for individuals suffering from Tourette's syndrome. Upon successful completion of these preclinical studies, management anticipates entering phase 1 and phase 2 clinical studies in 2014.

Price Target $14

We are maintaining our Buy rating on the shares of Neurocrine. While we are clearly disappointed in the outcome of the KINECT-1 study, pushing back the launch timelines of the drug by only twelve months has minimal impact on our DCF model. The added costs of KINECT-3 ($8-10 million) are easily supported by the existing cash balance, which stood at $157 million as of September 30, 2013.

Besides NBI-98854, Neurocrine obviously still has elagolix pushing forward at AbbVie (ABBV), and early-stage collaborations with Boehringer Ingelheim around the research and development of G-protein coupled receptor (GPCR) small molecules for the treatment of Type-2 diabetes. Phase 2 data on elagolix were just recently published electronically ahead of print in the Journal of Endometriosis and Pelvic Pain Disorders. We believe elagolix is worth $8-10 per share based on the rate at which the two ongoing phase 3 studies at AbbVie enroll and report data, and the timelines for the uterine fibroids phase 3 study.

PROJECTED FINANCIALS

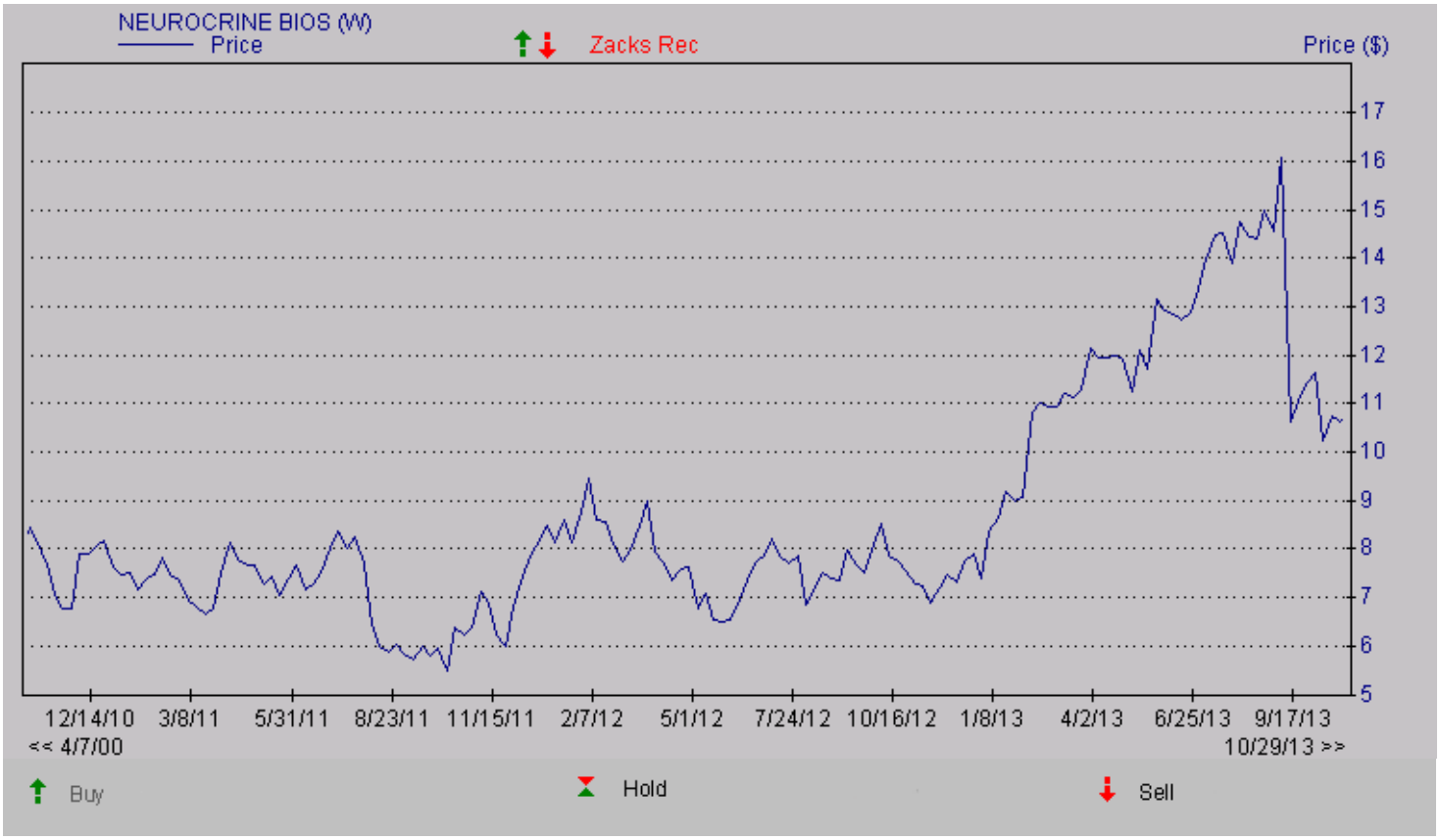
Neurocrine Biosciences Inc.
Income Statement

Neurocrine Bio	2011 A	2012 A	Q1 A	Q2 A	Q3 A	Q4 E	2013 E	2014 E	2015 E	2016 E
R&D / Milestones & Fees	**$77.4**	**$53.1**	**$0.7**	**$0.7**	**$0.7**	**$0.8**	**$2.9**	**$5.0**	**$50.0**	**$50.0**
YOY Growth	*131.1%*	*-31.4%*	*-93.5%*	*-93.4%*	*-92.2%*	*-96.6%*	*-94.5%*	*71.9%*	*900.0%*	*0.0%*
elagolix Royalties	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
VMAT-2	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$77.4**	**$53.1**	**$0.7**	**$0.7**	**$0.7**	**$0.8**	**$2.9**	**$5.0**	**$50.0**	**$50.0**
YOY Growth	*131.1%*	*-31.4%*	*-93.5%*	*-93.4%*	*-92.2%*	*-96.6%*	*-94.5%*	*71.9%*	*900.0%*	*0.0%*
CoGS / Royalties	$0	$0	$0	$0	$0	$0	$0	$0	$0.0	$0.0
Gross Margin	*100.0%*	*100.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*100.0%*	*100.0%*	*100.0%*	*100.0%*
SG&A	$12.4	$14.5	$3.4	$3.4	$3.2	$3.4	$13.4	$14.5	$15.0	$15.5
% SG&A	*16.0%*	*27.3%*	*464.7%*	*485.7%*	*445.1%*	*453.3%*	*461.9%*	*290.0%*	*30.0%*	*31.0%*
R&D	$31.0	$37.2	$10.3	$10.5	$9.5	$9.5	$39.8	$35.0	$40.0	$40.0
% R&D	*40.0%*	*69.9%*	*1412.7%*	*1500.0%*	*1301.8%*	*1266.7%*	*1368.3%*	*700.0%*	*80.0%*	*80.0%*
Operating Income	$34.1	$1.4	($13.0)	($13.2)	($12.0)	($12.2)	($50.3)	($44.5)	($5.0)	($5.5)
Operating Margin	*44.0%*	*2.7%*	-	-	-	-	*-1730.2%*	*-890.0%*	*-10.0%*	*-11.0%*
Interest / Other Income	$3.6	$3.6	$0.9	$0.9	$0.9	$1.0	$3.7	$3.5	$2.5	$2.5
Pre-Tax Income	$37.6	$5.0	($12.1)	($12.3)	($11.1)	($11.2)	($46.7)	($41.0)	($2.5)	($3.0)
Taxes	$0	$0	$0	$0	$0	$0	$0	$6.2	$0.8	$0.9
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5%*	*15.0%*	*30.0%*	*30.0%*
Net Income	$37.6	$5.0	($12.1)	($12.3)	($11.1)	($11.2)	($46.7)	($34.9)	($1.8)	($2.1)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	*48.5%*	*9.5%*	-	-	-	-	*-1603.9%*	*-697.0%*	*-3.5%*	*-4.2%*
Reported EPS	**$0.67**	**$0.08**	**($0.18)**	**($0.18)**	**($0.17)**	**($0.17)**	**($0.69)**	**($0.52)**	**($0.02)**	**($0.03)**
YOY Growth	-	*-88.5%*					*-1005.3%*	*-25.6%*	*-95.3%*	*16.0%*
Shares Outstanding	56.3	65.6	66.6	66.9	67.199	67.0	67.3	67.6	72.5	75.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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